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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,376	07/01/2003	John S. Patton	0005.15	3703

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NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,376	PATTON ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the decision in the appeal conference, the previous final office action is withdrawn. The following is the new office action.

Claims included in the prosecution are 26-43.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 31-33 and 39-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Backstrom (5,506,203).

Backstrom discloses insulin powder compositions containing at least 50 % insulin. The particle sizes are below 10 microns. One of the carrier materials is lactose (examples and claims). Although Backstrom does not specifically teach the moisture content, since it is a dry powder, it is the examiner's position that it will not have any moisture at all.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 26-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Backstrom cited above.

Backstrom as pointed out above discloses insulin powder compositions containing at least 50 % insulin. The particle sizes are below 10 microns. One of the carrier materials is lactose. The method of preparation involves preparing a solution of insulin a buffer solution and drying the product either by spray drying or freeze drying (examples; col. 7, line 24 through col. 8, line 41 and claims). Although in examples, Backstrom uses higher concentrations of insulin to prepare solutions, on col. 8, line 26, he teaches that that insulin has to be first dissolved in a solvent it would have been obvious to one of ordinary skill in the art to use appropriate amounts of insulin in the solution and then spray dry the solution with a reasonable expectation of success. Although Backstrom does not teach sodium citrate specifically, on col. 7, line 33 teaches pH adjusting compounds and since citrate is used in citrate buffer preparations, it would have been obvious to use this pH adjusting compound with a reasonable expectation of success.

4. Claims 28-30, 34, 36, 38 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Backstrom cited above in combination with JP 56 138 110 of record.

The teachings of Backstrom have been discussed above. Backstrom although teaches pH adjusting compounds, does not teach sodium citrate. The use of sodium citrate in the compositions of Backstrom would have been obvious to one of ordinary skill in the art since JP teaches that the mucosal absorption of insulin is improved by this buffer (abstract).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 31-34 and 39-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-29, 32-33, 35-49 and 51-58 of copending Application No. 10/245,705. Although the conflicting claims

are not identical, they are not patentably distinct from each other because claim 28 in the copending application are drawn to generic pharmaceutical agent in an amorphous dry powder form having the particle sizes of less than 10 microns and claims 32 and 33 identify insulin as one of the pharmaceutical agents. Claim 41 further identifies the composition is a spray dried composition; instant claims drawn specifically to insulin and in specific amounts therefore, are anticipated by the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that a non-statutory obviousness-type double patenting rejection of claim 31 would be appropriate only if claim 31 is ether anticipated by or would have been obvious only if claim 31 is either anticipated by or would have been obvious over a claim in the 705 application and neither is the case here. These augments are not persuasive. Claim 28 in 705 is generic with respect to the active agent. However, the dependent claims in 705 recite insulin and therefore, it is evident that claim 28 in 705 includes insulin. Claim 28 in 705 is generic with respect to the amounts and therefore, instant amounts of insulin, that is 20 to 80%, are anticipated by the claims in 705. Furthermore, one of ordinary skill in the art would be motivated to change the amounts of insulin and the excipient to obtain the best possible results and such changes would have been obvious to one of ordinary skill in the art.

7. Claims 31-34 and 39-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-43 of copending Application No. 10/245,706. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are drawn to insulin composition in a carrier buffer in a powder form suitable for administration by inhalation. The dependent claim 32 identifies the particle sizes to be less than 10 microns. The dependent claim 28 identifies the buffer to be trehalose, lactose and other sugars. Instant claims are drawn to powdered amorphous insulin compositions with particle sizes below 10 microns and with moisture content of below 10 % containing the same carbohydrate material. The claims in the copending application thus, are generic with respect to the amounts of insulin and the particle sizes and therefore, instant claims are anticipated by the claims in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is maintained since contrary to applicant's arguments, the double patenting rejection is not the only rejection in this application.

8. Claims 31-34 and 39-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of U.S. Patent No. 6,358,530 in combination with Rubsamen (5,364,838). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in said patent are drawn to generic polypeptide active agent and instantly claimed insulin is a polypeptide. One of ordinary skill in the art would be motivated to

use insulin as the polypeptide with a reasonable expectation of success since the reference of Rubsamen shows that insulin is administered as a powder in an aerosol form for pulmonary delivery. In the patented claims, one of the excipients claims is a carbohydrate and the dependent claim 5 identifies the carbohydrate to be lactose, trehalose and others just as in instant claims. The patented claims are generic with respect to the amount of the polypeptide and instant amounts of insulin are therefore, anticipated by the patented claims. The patented claims do not exclude the presence of buffers such as sodium citrate in instant claims.

9. Claims 31-34 and 39-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 13-16 of U.S. Patent No. 5,997,848. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in said patent and instant claims recite the same insulin compositions. The patented claims however, are drawn to a method of delivering insulin. In the dependent patented claim 5, the insulin is present in an amount of 5 to 99 % and the particles and the particles are less than 10 microns in diameter. The carrier material is either a carbohydrate, organic salt or an amino acid. The patented claims are generic with respect to the amount of insulin and the carrier and therefore, instant claims are anticipated over the claims of said patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G Kishore/

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK